PFEIFFER CONSULTING -
"One Stop" Regulatory Solution for
European Union Cosmetic Compliance

EUROPEAN UNION REGULATORY SOLUTIONS

ABOUT US

Pfeiffer Consulting GmbH is a "one stop" consultancy for cosmetic companies who wish to break into the EU market.

WE ASSIST WITH:

- EU Regulatory services
- Implementing ISO 22716
  (Cosmetic Good Manufacturing Practices)
- Cosmetic GMP Verification
- Additionally –
  - Product development and manufacturing
  - Quality assurance
  - Training and Education
  - We provide support for establishing high efficiency cosmetic production processes.

OUR EXTENSIVE NETWORK

Pfeiffer Consulting GmbH is a privately owned consulting firm that has branches in the following countries:

- Headquarter – Pfeiffer Consulting GmbH, Straubenhardt, Germany
- Pfeiffer Consulting LLC – Bonita Springs, FL, USA
- Pfeiffer Consulting – Eastern Europa, Plovdiv, Bulgaria

Additionally Pfeiffer Consulting has strategic partnerships with multiple independent consultancies such as:

- LEMIKOS GmbH – A highly regarded consultancy specialized in EU Cosmetic Safety Assessments.
- SYNERGYNAPEX LLC – an international business development consultancy based in Tampa, FL with special focus on natural cosmetics.
- PRIVATE LABELERS worldwide for production for large variety cosmetic products
- Consultancies that assist with product development, marketing and sales

WHAT SETS US APART?

EU Cosmetic Compliance has become a major income area for consultants where costs and quality vary substantially. The field is dominated mainly by large players with advertising budgets that ultimately reflect in their costs. There are also less qualified businesses that may offer lower rates but may be of questionable quality and/or reputation. Pfeiffer Consulting balances the needs for budget friendly solutions with exceptional quality and thoroughness.

Pfeiffer Consulting is based in Germany and all documentation generated in Germany is highly regarded within EU region.

We are flexible and can accommodate small to medium size companies. You will be provided with customized services.

We are looking to build long-term relationships rather than one – off projects. We treat our customers as an extension of our business.

OUR DIFFERENCE SUMMARIZED

- Cost
- Flexibility
- Accuracy
- Quality Standard

EU REGULATORY COMPLIANCE

WHAT IS REQUIRED TO SELL IN EU?

Three Steps are clearly listed in the EU Cosmetic Regulation 1223/2009:

- Create Product Information Files and Safety Assessments
- Create a system for the Responsible Person requirement
- Complete notification with the Notification Portal (known as CPNP)

PRODUCT INFORMATION FILE (PIF)

WHAT IS A PRODUCT INFORMATION FILE? (PIF) ?

PIF is a folder that lists key information for each SKU sold in EU that must be accessible within approx. 48 hours notice by authorities.

The **PIF is made of FIVE PARTS** of each finished product:

- Its **RAW MATERIALS**
- The actual **FINISHED PRODUCT**
- Its **PACKAGING**
- **GMP CERTIFICATE** (of the facility)
- A product **SAFETY ASSESSMENT**

PIF – RAW MATERIALS

The PIF needs to contain information about each raw material used in the finished product. These are:

- Certificate of Analysis / Product specification
- Information regarding
  - Quantitative composition with INCI name
  - Vendor's production process (a non-proprietary short description is sufficient)
  - Physical / chemical / microbiological properties
  - (If unavoidable) possible impurities
  - MSDS – with toxicological data referencing raw material
  - Spray Products (Inhalation data.)
  - Exact content % also of incremental (if preserved with preservative/antioxidant etc.)

PIF - RAW MATERIALS…CONT'D.

- Nano related information (if applicable)
- Fragrance evaluation
  - IFRA class
  - Safety evaluation from vendor with usage details based on maximum concentration details
  - Quantitative content of EU defined Allergens (currently 26, such as linalool, limonene etc.)

PIF – FINISHED PRODUCT

PIF – FINISHED PRODUCT

- SKU number and matching formula SKU number
- Qualitative and Quantitative Formula
- Product specifications of bulk / finished product
- Label, art work, advertising with respect to efficacy, use instructions
- Product samples MAY be required.
- Shelf Life / Period after opening information
- Tests
  - Stability
  - Micro
  - Challenge tests (in particular for water rich products)
  - Dermatological tests
  - Efficacy (if claims are made)
  - For Aerosols PSD Test (Particle Size Distribution)

PIF – PACKAGING MATERIAL

PACKAGING MATERIAL

- Composition / What is it made of?
- Test reports about stability tests in packaging
- Suitability (that the packaging is appropriate) for specific cosmetic formula
- MSDS sheets and spec sheets
- Additional characteristics (quality, purity, stability….)

PIF – GMP

EU Cosmetic Regulations require that Cosmetic Producers adhere to good manufacturing practices

Since many governments do not issue Cosmetic GMP's the following can be accepted as verification of GMP compliance:

- A self - declaration with a copy of standard operating procedures
- (USA) FDA audit report
- An independent verification

  Pfeiffer Consulting Verification is recommended.

  Our services include:

  - Cosmetic-GMP audits
  - Implementing ISO 22716
  - Providing assistance with projects, especially in material and production management
  - Providing assistance with new constructions, reconstructions or conversions
  - Providing assistance for architects and building engineers
  - Construction and Fire Safety Inspection reports

PIF - SAFETY ASSESSMENT

PIF - WHAT IS THE SAFETY ASSESSMENT?

- Most important element in the PIF
- Can be only issued by a "qualified person" as described in EU Cosmetic Regulation.
- The "qualified person" must be an EU accredited chemist, biologist or similar.
- All information provided for PIF's will help the safety assessor to "asses safety" of each SKU.
- Safety Assessors can lose licenses if issuing wrongful reports thus this process is elemental in enforcing safe products in the EU market.

RESPONSIBLE PERSON

Once PIF are completed next step is deciding on the **RESPONSIBLE PARTY** administration

WHAT IS A RESPONSIBLE PERSON?

- A responsible person is the legally defined (regulatory requirement) link that connects the finished product to the CNPN database and is responsible to "report/manage" all aspects of product that may relate to human health/adverse effects.
- The address of the "responsible person/where PIF's are located" MUST be listed on the label.

RESPONSIBLE PERSON RECOMMENDATION

We recommend that **the manufacturer becomes their own RP**

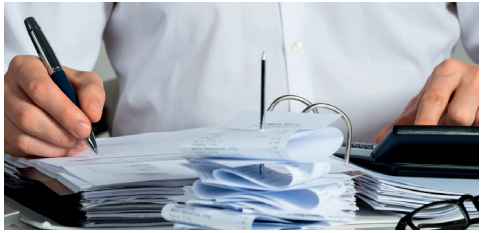
HOW?

- The manufacturer sets up their own company in EU and act as the responsible person
- Michael Pfeiffer is appointed as the "contact person" to liaise all communication to manufacturer and local authorities
- Then each distributor appoints the Manufacturer's EU company as their RP. (see EU Cosmetic Regulation Article 4, Section 5.)

RESPONSIBLE PERSON SERVICES

BENEFITS OF OUR SYSTEM

- No need to shop around for Responsible Person services
- No need to change address on labels if you start working with a new RP
- More cost effective long-term
- Distributors can focus on selling rather than regulatory



FINAL STEP - CPNP NOTIFICATION

- EU Cosmetic Regulations created a single European cosmetics database where the "first importer" is required to enter some information for all imported cosmetic products.
- The "first importer" (**unless centralized through our recommended RP system**) is technically each distributor that imports the products from a non-EU country.
- This is not a public database. Only "responsible persons" can enter data and the government officials can see the data.
- The data entered to CPNP is a summarized repeat of PIF's and labels. It is mainly a clerical function.

CPNP NOTIFICATION…CONT'D,

- As recommended in previous slide(s) our recommended system takes this administrative pressure from distributors / importers by centralizing a single RP for all importers.
- In our system, the distributors simply appoint YOUR EU company as their RP and as your secretary we undertake the CPNP notifications for each SKU imported to EU by any of your distributors/importers.

FAQ

The most common question from Non-EU producers is: **Are our documents sufficient to complete the EU Safety Assessment?**

ANSWER / SOLUTION:

- In our experience 80% of the documentation is usually easily available. The remaining 20% may need some additional work. (i.e. tests, contacting vendors etc.)
- For a nominal fee, we offer a document check service BEFORE we start a full project.
- It includes walking you through each document type in detail
  - Providing samples of formats.
  - Determine what additional documents may be needed.
  - A review of your existing documents

HOW LONG IS THE PROCESS?

Depending on the number of SKU's the typical cosmetic manufacturer with 50 to 100 SKU's can expect the full process to last approx. min. 2 max. to max. 6 months from the date all documents required are sent to Pfeiffer Consulting/LEMIKOS.

WHAT IS THE COST?

Several factors will influence the cost but the main factor will be availability of information and the complexity of each unique formulation. Therefore, to provide a quote we ask for the list of products and their INCI ingredient listings.

THE COST BASIS IS CALCULATED AS FOLLOWS:

- Document audit (Hourly rates apply)
- Preparing PIF 's (Approx. $150 per SKU)
- Safety Assessment (Cost start at approx. $300 per unique formulation)
- Responsible Person –
  - One time investment of approx. $500 for company formation
  - Annual recurring government fees of approx. $750 per year
  - Annual recurring fees for our services (to act as your secretary) approx. $500 to max. $3,000 per year depending on number of SKU's.

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